

§ 82.1710

21 CFR Ch. I (4–1–08 Edition)

§ 82.1710 D&C Yellow No. 10.

The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b) of this chapter.

[48 FR 39220, Aug. 30, 1983]

**Subpart D—Externally Applied
Drugs and Cosmetics**

§ 82.2050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.2051 Lakes (Ext. D&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, barium, or calcium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.
Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.
Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

- (1) The listed name of the color from which the lake is prepared;
- (2) The name of the basic radical combined in such color; and
- (3) The word "Lake." (For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is "Ext. D&C Yellow No. 2—Calcium Lake," and a lake

prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is "Ext. D&C Red No. 2—Barium Lake.")

§ 82.2707a Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of § 74.1707a(a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

PARTS 83–98 [RESERVED]

PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/NEW USES FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

Subpart A—General Information

- Sec.
99.1 Scope.
99.3 Definitions.

Subpart B—Information To Be Disseminated

- 99.101 Information that may be disseminated.
99.103 Mandatory statements and information.
99.105 Recipients of information.

Subpart C—Manufacturer's Submissions, Requests, and Applications

- 99.201 Manufacturer's submission to the agency.
99.203 Request to extend the time for completing planned studies.
99.205 Application for exemption from the requirement to file a supplemental application.

Subpart D—FDA Action on Submissions, Requests, and Applications

- 99.301 Agency action on a submission.
99.303 Extension of time for completing planned studies.
99.305 Exemption from the requirement to file a supplemental application.

Subpart E—Corrective Actions and Cessation of Dissemination

- 99.401 Corrective actions and cessation of dissemination of information.
99.403 Termination of approvals of applications for exemption.